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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/506,543	10/13/2004	Kjell Olmarker	003301-175	1315
21839 7590 02/08/2007 BUCHANAN, INGERSOLL & ROONEY PC POST OFFICE BOX 1404 ALEXANDRIA, VA 22313-1404			EXAMINER MONDESI, ROBERT B	
			ART UNIT	PAPER NUMBER
			1652	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		02/08/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/506,543

Applicant(s)

OLMARKER, KJELL

Examiner

Robert B. Mondesi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 November 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25-48 is/are pending in the application.
- 4a) Of the above claim(s) 25-45 and 47-48 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☒ Certified copies of the priority documents have been received in Application No. 1092919.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date See Continuation Sheet.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :July 20, 2006 and October 13, 2004.

DETAILED ACTION

Response to restriction requirement

Applicants' election with traverse of Invention XVII, **Claim 46** in amendment, filed November 22, 2006 is acknowledged. The traversal is on the ground(s) that all the claims relate to a substance or use of a substance that inhibits pro-inflammatory cytokine(s) to improve and encourage wound healing. Thus the applicants submit that inventions of groups I-XVII are closely related and that a proper search of any of the claims should by necessity, require a proper search of others. This is not found persuasive because the compounds involved in the various methods of the instant application are not only classified in different classes but also have little in common and would not be cited in the same reference for example, lactoferrin is used for the treatment of wounds and has no structural or functional similarity with prostaglandis, melanin or melacortin agonists. Melacortin and its agonists are used for the treatment of obesity, melanin is a primary determinant of skin color whereas prostaglandis is involved in smooth muscle contraction.

Therefore the requirement is still deemed proper and is made FINAL. **Claims 25-48** are pending in this application. **Claims 25-45 and 47-48** are withdrawn from further consideration because these Claims are drawn to non-elected inventions. **Claim 46** is currently under examination.

Priority

The current application filed on is a 371 of PCT/SE03/00347 filed on 03/04/2003 which is a CON of 10/092,919 filed on 03/08/2002, which in turn claims priority to

foreign application, SWEDEN 0200667-4 filed on 03/05/2002. A certified copy of foreign document SWEDEN 0200667-4 has been provided.

Preliminary Amendment

The preliminary amendment filed October 13, 2004 has been entered.

Information Disclosure Statement

The IDS filed July 20, 2006 and October 23, 2004 have been received and are signed and considered, a copy of the PTO 1449 is attached to the following document.

Specification

The disclosure is objected to because of the following informalities:

The use of the trademarks APOZEPAM, MEBUMAL VET (page 5, lines 31-32) HYPNODIL, KETALAR, STERSNIL (page 6, lines 20-24), HUMICADE, ROQUININEX, ARIFLO, ORTHEGEN, ORTHOKIN (page 10, line 3 and 34) have been noted in this application. They should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Appropriate correction is required.

Claim Objections

Claim 46 is objected to because of the following informalities: **Claim 46** depends from a nonelected claim. Applicants need to amend **claim 46** so it includes all the limitations of nonelected claim, **claim 25** that it depends from.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 46 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claim is drawn to peptide derivatives of lactoferrin. The claim does not require that the polypeptide possess any particular conserved structure, or other distinguishing feature, such as a specific biological activity. Thus, the claim is drawn to a genus of polypeptides that is defined by an unclear functional relationship to lactoferrin. To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, and any combination thereof. In this case, the only factor present in the claim that is sufficiently disclosed is that the said derivatives inhibit pro-inflammatory cytokine when administered to a patient. The specification does not identify any particular portion of the structure that must be characteristics of the claimed genus are not described. The only

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adequately described species is lactoferrin and no active variants are disclosed.

Accordingly, the specification does not provide adequate written description of the claimed genus.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states, "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the "written description" inquiry, whatever is now claimed." (See page 1117.) The specification does not clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116), As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of polypeptides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016. One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence. Therefore, only lactoferrin, but not the full breadth of the claim meets the written description provision of 35 U. S.C. 112, first paragraph. Applicant is reminded

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that *Vas-cath* makes clear that the written description provision of 35 U.S.C. § 112 is severable from its enablement provision.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 46 is rejected under 35 U.S.C. 102(e) as being anticipated by Reuben et al. United States Patent Application Publication US 2002/0072596.

Reuben et al. teach a method of treating hypertrophic scars and keloids (wounds) comprising the step of administering peptides derived from lactoferrin (page 4, section 0041; page 63, section 05900. Reuben et al. teach further that the lactoferrin derived peptides of their invention can be used in a method of treatment for post traumatic tissue injury caused by surgery or a pathological condition with scar formation wherein the scar formation is caused by a vascular disease (page 63, 0590, 0591, 0593) Reuben et al. also teach that peptides derived from lactoferrin can be administered locally (page 63, section 0594 and 0595). Reuben et al. teach that peptides derived from lactoferrin can be used to modify the activity of molecules such as TNF and IL-1

(page 28, section 0024). Thus Reuben et al. teach all the elements of **claim 46** and this claim is anticipated under 35 USC 102(e).

Claim 46 is rejected under 35 U.S.C. 102(b) as being anticipated by Mita et al., US Patent No. 5,561,109.

Mita et al. teach a method of treating wounds, which includes the administering of lactoferrin (claim 1 of US. Patent No. 5,561,109).

Thus Mita et al. teach all the elements of **claim 46** and this claim is anticipated under 35 USC 102(b).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 46 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over **claims 1 and 23** of copending Application No. 10/092,919. Although the conflicting claims are not identical, they are not patentably distinct from each other because **claim 46** of the present application is drawn to a method of treating a wound and or improving wound healing comprising administering a substance that inhibits a pro-inflammatory cytokine, wherein the substance is lactoferrin or a peptide derived form lactoferrin and **claims 1 and 23** of copending Application No. 10/092,919 are drawn to a method of or reduction of adhesion comprising the active step of administering a substance that inhibits a pro-inflammatory cytokine, wherein the substance is lactoferrin or a peptide derived form lactoferrin. Therefore, it is apparent that even though the intended methods of the two inventions, as stated in the preamble, may differ slightly, the actual active method step of both inventions is identical and would necessarily bring about the same effect.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert B. Mondesi whose telephone number is 571-272-0956. The examiner can normally be reached on 9am-5pm, Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 571-272-0928. The fax

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phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Robert B Mondesi
Examiner
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1-22-07